37. (Amended) A stabilized pharmaceutical composition comprising an active component consisting essentially of atorvastatin calcium and about 40% or greater by weight of the composition of an amido-group or amino-group containing polymeric stabilizer.

**Please add the following new claims:**

40. (New) The stabilized pharmaceutical composition of claim 36, wherein the amount of pravastatin sodium ranges from about 7 to about 11 percent by weight of the composition.

41. (New) The stabilized pharmaceutical composition of claim 37, wherein the amount of atorvastatin calcium ranges from about 7 to about 11 percent by weight of the composition.

## REMARKS

Claims 1-39 are currently pending in the application. New claims 40-41 have been added. Thus, upon entry of this amendment, claims 40-41 will be pending. No new matter has been added. Moreover, the new claims are more narrowly tailored aspects of the invention that do not raise any new issues of patentability. Entry of these amendments and new claims is therefore respectfully requested.

Applicants would like to thank the Examiner for extending the courtesy of an interview on October 8, 2002. Applicants have amended the claims in accordance with the Examiner's suggestions. Applicants have also clarified some of the recitations in the claims without narrowing their scope.

### I. Rejection Under 35 U.S.C. § 102(b)

Claim 1 has been rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,627,200 to Kreutter et al. The Examiner states that Kreutter does not teach a composition having a stabilizer in addition to applicant's claimed stabilizer. Applicant respectfully traverses the rejection.

Kreutter discloses a composition in which the primary active ingredient is a $\beta_3$-adrenoceptor antagonist or agonist. However, as the Examiner acknowledges, Kreutter does not disclose an active component consisting essentially of one or more compounds selected from the group consisting of (i) a ring-opened 7-substituted-3,5-dihydroxyheptanoic acid or a pharmaceutically acceptable acid salt thereof, and (ii) a ring-opened 7-substituted-3,5-dihydroxyheptenoic acid or a pharmaceutically acceptable acid salt thereof. Therefore, Applicant respectfully requests withdrawal of the rejection under § 102(b).

## II. Rejection Under 35 U.S.C. § 103 Over Kreutter

Claims 1-39 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Kreutter. Applicants respectfully disagree. Assuming *arguendo* that Kreutter discloses the various components of the claimed composition, it would not have been obvious to one of ordinary skill in the art to combine these components, without any motivation, to arrive at the claimed composition while excluding the primary active ingredient of Kreutter, a $\beta_3$-adrenoceptor antagonist or agonist.

## III. Rejection Under 35 U.S.C. § 103 Over Tsujita

Claims 1-37 were rejected under § 103(a) as being unpatentable over U.S. Patent No. 5,627,375 to Tsujita et al. The Examiner states that Tsujita teaches the optional use of PVP and does not teach a composition that has another stabilizer or combination of stabilizers. Applicant respectfully traverses this rejection.

Like Kreutter, Tsujita is directed to a different composition than that of the claimed invention. Tsujita is directed toward a synergistic combination of HMG-CoA reductase inhibitors and insulin sensitizers for the treatment of arteriosclerosis and xanthoma. Assuming *arguendo* that Tsujita discloses the various components of the claimed composition, it would not have been obvious to one of ordinary skill in the art to combine these components, without any motivation, to arrive at the claimed composition while excluding a critical ingredient of Tsujita, an insulin sensitizer.

## IV. Conclusion

In view of the foregoing amendments and remarks, Applicant believes that the application is now in condition for allowance and prompt reconsideration and allowance is earnestly requested.

If the Examiner has any questions or wishes to discuss this application, please telephone the undersigned at the number indicated below.

Respectfully submitted,

Dated: 11/25/02

W. David Wallace
Reg.No. 42,210

KENYON & KENYON
1500 K Street, NW
Washington, DC 20005
202.220.4200

DC01 432094

Marked-Up Version of Amendments

1. (Amended) A stabilized pharmaceutical composition for the treatment of dyslipidemia, comprising

[as] an active component consisting essentially of one or more compounds selected from the group consisting of [at least one] (i) a ring-opened 7-substituted-3,5-dihydroxyheptanoic acid or a pharmaceutically acceptable acid salt thereof, and (ii) a ring-opened 7-substituted-3,5-dihydroxyheptenoic acid[,]or a pharmaceutically acceptable acid salt thereof, and

a stabilizing effective amount of at least one amido-group containing polymeric compound or at least one amino-group containing polymeric compound, or combination thereof, wherein said stabilized pharmaceutical composition does not contain a stabilizing effective amount of another stabilizer or a combination of other stabilizers.

26. (Amended) A stabilized pharmaceutical composition for the treatment of dyslipidemia comprising, in admixture,

(a) an active component consisting essentially of about 0.05% to about 70% by weight of [a] one or more compounds selected from the group consisting of (i) a ring-opened 7-substituted 3,5-dihydroxyheptanoic acid or a pharmaceutically acceptable acid salt thereof or (ii) a ring-opened 7-substituted-3,5-dihydroxyheptenoic acid or a pharmaceutically acceptable acid salt thereof, and

(b) about 30% to about 99% by weight of a stabilizing effective amount of an amido-group containing polymeric compound or a stabilizing effective amount of an amino-group containing polymeric compound, or combination thereof, wherein said stabilized pharmaceutical composition does not contain a stabilizing effective amount of another stabilizer or a combination of other stabilizers.

36. (Amended) A stabilized pharmaceutical composition comprising an active component consisting essentially of pravastatin sodium and about 40% or greater by weight of the composition of an amido-group or amino-group containing polymeric stabilizer.

37. (Amended) A stabilized pharmaceutical composition comprising an active component consisting essentially of atorvastatin calcium and about 40% or greater by weight of the composition of an amido-group or amino-group containing polymeric stabilizer.